

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF MISSISSIPPI  
EASTERN DIVISION

CHARLES D. WHITEHEAD, et al.,

Plaintiff,

v.

NO. 1:97CV29-S-D

HENRY L. EDMONDSON, M.D., et al.,

Defendants.

OPINION

In this case, plaintiffs, the alleged wrongful death beneficiaries of Michael S. Whitehead, claim that defendants violated the Clinical Laboratory Improvement Act (CLIA), 28 U.S.C. § 263a, and are liable for negligence per se and for failure to diagnosis and treat decedent's medical condition. In making these allegations, plaintiffs invoked only this court's federal question jurisdiction under 28 U.S.C. § 1331. Presently before the court is defendants' motion to dismiss based on lack of subject matter jurisdiction and failure to state a claim for relief. Specifically, defendants maintain that CLIA does not provide a private cause of action for alleged violations of its provisions and, alternatively, that if CLIA does provide such a right, four of the five instant plaintiffs are not properly before the court as wrongful death beneficiaries.

After carefully considering the matter, the court is of the opinion that a plain reading of the statute clearly indicates that CLIA does not provide a private cause of action to individuals seeking relief for its alleged violation and that no such implicit right of action exists. Indeed, nearly every provision of that act directly delegates oversight of clinical laboratories to the Secretary of Health

and Human Services and to no one else. *See, e.g.*, 28 U.S.C. § 263a(b) (Secretary must issue certificate allowing laboratory to conduct certain tests); 28 U.S.C. § 263a(d)(1)(D) (Secretary has authority to inspect laboratory records); 28 U.S.C. § 263a(d)(2)(B) (Secretary must be notified of changes in laboratory examinations and procedures); 28 U.S.C. § 263a(e) (Secretary approves and disapproves laboratory accreditation body); 28 U.S.C. § 263a(f)(1) (Secretary issues standards “to assure consistent performance by laboratories issued a certificate under this section of valid and reliable laboratory examinations and other procedures”); 28 U.S.C. § 263a(g)(1) (Secretary may conduct planned or surprise inspections); 28 U.S.C. § 263a(n) (Secretary “shall compile and make available to physicians and the general public information...which the Secretary determines is useful in evaluating the performance of a laboratory....”).

Furthermore, and of particular importance in this court’s mind, are the provisions dealing with laboratories which are in noncompliance with the Secretary’s standards. In that instance, only the Secretary may impose intermediate sanctions, including monetary civil penalties, 28 U.S.C. § 263a(h)(1) and (2); suspend, revoke, or limit certification of the laboratory, 28 U.S.C. § 263a(i)(1) and (2); or seek to enjoin the laboratory from continuing activity which creates a significant hazard to the public health, 28 U.S.C. § 263a(j). The United States Attorney General may also prosecute anyone intentionally violating the provisions of CLIA or its regulations. 28 U.S.C. § 263a(l). These provisions directly give enforcement authority over clinical laboratories to the Secretary and the Attorney General and make no mention, either directly or implicitly, of an individual’s right to seek damages or injunctive relief against a laboratory for its alleged failures.

There are no cases addressing the precise issue before the court, but in support of their position, plaintiffs primarily rely upon *Consumer Federation of America v. Department of Health*

*and Human Services*, 906 F. Supp. 657 (D.D.C. 1995). As defendants point out, however, that reliance is misplaced, as *Consumer Federation* addressed the issue of standing in the context of the Administrative Procedure Act, not CLIA, and did not speak to the matter at hand. Finally, although the court does not believe it necessary to look to the legislative history of CLIA for a resolution of the instant issue, it notes that the history supports the court's interpretation of that act. *See* H.R. Rep. No. 899 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3829 and 3831.

Therefore, after careful consideration, the court finds that because CLIA does not provide a private right of action to individuals, plaintiffs have failed to state a claim upon which relief can be granted, and the motion to dismiss is well taken. The court need not address defendants' alternative theory of relief. Since the court has dismissed the claim forming the jurisdictional basis for this action, it declines to exercise its supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367, a basis of jurisdiction which, the court notes, plaintiffs failed to invoke.

An appropriate order and final judgment shall issue.

This 24th day of March, 1998.

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CHIEF JUDGE